K063548

510(k) Summary

JAN 2 2 2007

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name:COR Analyzer I

Establishment Name and Registration Number of Submitter

Name: Rcadia Ltd. (Rcadia hereafter)
Registration: In process
Submission contact: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	LLZ
Regulation Number:	892.2050
Common Name:	PACS - Picture archiving &communications system
Classification Name:	Picture archiving and communications system
Regulatory class:	Class II

Reason for 510(k) Submission
Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices
K061624 *Vitrea2*

Device Description
COR Analyzer I is a post processing software application which runs on a stand-alone Windows based work-station. The device input is Computed Tomography Angiography (CTA) set of images. The received data is displayed on the workstation screen, reviewed and selected by the operator for processing. The application enables interactive user–software process in which the user chooses a CT slice, points on the selected coronary vessel and the software present the entire selected vessel as a stretched image. In a reversed process, the user can mark a ~~specific point on the stretched vessel~~ and the software retrieves and displays the original correspondent CT slice. COR Analyzer I output results can be stored for future analysis.

Indications for use
The COR Analyzer I is intended to assist a trained physician to analyze Computed Tomography (CT) Angiographic images. The COR Analyzer I is specifically indicated to provide visualization of the major coronary vessels and lesions, thus assisting the physician in visualizing the coronary anatomy and pathology. COR Analyzer I has abilities for coronary vessels segmentations, abnormalities display and processing.

Safety & Effectiveness
The device has been designed, verified and validated complying with 21CFR 820.30 regulations. Bench and clinical data demonstrate that the COR Analyzer I meets the required specifications. No adverse affects have been detected.

Substantial Equivalency
It is Rcadia Medical Imaging Ltd. opinion that the COR Analyzer I is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 22 2007

Mr. Dan Laor
Official Correspondent
Rcadia Medical Imaging Ltd.
Derech Yafo 157
Haifa, 35251
ISRAEL

Re: K063548
Trade/Device Name: COR Analyzer I
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: LLZ and JAK
Dated: November 20, 2006
Received: November 24, 2006

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 063548

Device Name: COR Analyzer I

Indications For Use:

The COR Analyzer I is intended to assist a trained physician to analyze Computed Tomography (CT) Angiographic images. The COR Analyzer I is specifically indicated to provide visualization of the major coronary vessels and lesions, thus assisting the physician in visualizing the coronary anatomy and pathology. COR Analyzer I has abilities for coronary vessels segmentations, abnormalities display and processing.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063548